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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,316	06/27/2007	**Kenichi Higashiyama**	47233-5008	9446

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EXAMINER	
MACAULEY, SHERIDAN R	
ART UNIT	PAPER NUMBER
1651	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/591,316	HIGASHIYAMA ET AL.	
	Examiner	Art Unit	
	SHERIDAN R. MACAULEY	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☒ Claim(s) *1* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-8 are pending and examined on the merits in this office action.

Claim Objections

1. Claim 1 is objected to because of the following informalities. It is recommended that the claim be amended as follows: The abbreviation “AN/TN ratio" should be fully written out before its first use, such as by reciting "amino nitrogen to total nitrogen (AN/TN) ratio". Appropriate correction is required.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a

question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 1 recites the broad recitation “65% or less”, and the claim also recites “43% or less” and “”35% or less”, which are the narrower statements of the range/limitation.

4. Claim 9 is also rendered indefinite by the recitation of “astaxanthin is stored at a concentration of..." It is unclear whether applicant intends to recite an additional storage step in the claimed method or whether applicant intends to claim that the process results in a product with the specified concentration of astaxanthin. If applicant intends the former, it is recommended that the claims be amended to recite "further comprising the step of storing..." or some other appropriate terminology. If applicant intends the former, it is recommended that the claims be amended to recite "wherein astaxanthin is produced at a concentration of..." or some other appropriate terminology.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1 and 3-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP3163127 (see English abstract) in view of Yamanka (US 3,882,635). Claim 1 recites a process for producing astaxanthin-containing lipids which comprises culturing green alga with an organic nitrogen source being used in a medium at an AN/TN ratio of 65% or less, preferably 43% or less, more preferably 35% or less, to obtain algal bodies in which astaxanthin-containing lipids have been stored. Claim 3 recites the process according to claim 1, wherein the organic nitrogen source is at least one organic nitrogen source selected from the group consisting of corn steep liquor, soya bean

powder, peptone, tripeptone, and polypeptone. Claim 4 recites the process according to claim 1, wherein the organic nitrogen source is used at least 0.1 g/L. Claim 5 recites the process according to claim 4, wherein culture is performed in a reactor under the dark condition. Claim 6 recites the process according to claim 5, wherein culture is performed under aerobic conditions. Claim 7 recites the process according to claim 4, wherein culture is performed in a reactor under the light condition or in an outdoor, closed system. Claim 8 recites the process according to claim 5, wherein astaxanthin is stored at a concentration of at least 10 mg/L of the culture solution or at least 40 pg/cell.

9. JP3163127 teaches a process for producing astaxanthin that comprises culturing green alga with an organic nitrogen source to obtain algal bodies in which the astaxanthin, which would be contained in lipids, has been stored (see English abstract). The reference teaches that organic nitrogen used in the process is yeast extract at a concentration of 2 g/L (see English abstract). The reference teaches that culture is performed under aerobic conditions and may be performed in a reactor under light or dark conditions (see English abstract). The method of the reference does not teach the specific AN/TN ratio of the organic nitrogen source, and does not teach the use of the nitrogen sources recited in the claims.

10. Yamanaka teaches a process for producing green algae wherein the alga is cultured with an organic nitrogen source, wherein the organic nitrogen source comprises peptone (col. 3, example 1).

11. At the time of the invention, a process for producing astaxanthin comprising nearly all of the claimed steps was known, as taught by JP3163127. It was also known

that green algae could be grown using organic nitrogen sources, as taught by JP3163127 and Yamanaka. One of ordinary skill in the art would have been motivated to alter the organic nitrogen sources to use a source with the claimed AN/TN range, such as peptone, because Yamanaka teaches that green alga can be grown with a variety of nitrogen sources including peptone (col. 2. lines 61-col. 3, line 2). One would therefore have achieved the claimed ratio in the course of routine optimization. One would have had a reasonable expectation of success in combining the teachings discussed above to arrive at the claimed method because green alga, particularly those producing astaxanthin, were known to be compatible with organic nitrogen at the time of the invention, as taught by JP3163127 and Yamanaka. It would therefore have been obvious to combine the teachings of the prior art to arrive at the claimed invention.

12. Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP3163127 (see English abstract) in view of Yamanka (US 3,882,635) as applied to claims 1 and 3-8 above, and further in view of Tanaka (WO 02/077105; see English translation US 2004/0091524 A1). Claims 1 and 3-8 are discussed above. Claim 2 recites the process according to claim 1, further including the steps of extracting the astaxanthin-containing lipids from the algal bodies and optionally purifying the extracted lipids.

13. JP3163127 teaches a process for producing astaxanthin that comprises culturing green alga with an organic nitrogen source to obtain algal bodies in which the astaxanthin, which would be contained in lipids, has been stored (see English abstract).

The reference teaches that organic nitrogen used in the process is yeast extract at a concentration of 2 g/L (see English abstract). The reference teaches that culture is performed under aerobic conditions and may be performed in a reactor under light or dark conditions (see English abstract). The method of the reference does not teach the specific AN/TN ratio of the organic nitrogen source, and does not teach the use of the nitrogen sources recited in the claims.

14. Yamanaka teaches a process for producing green algae wherein the alga is cultured with an organic nitrogen source, wherein the organic nitrogen source comprises peptone (col. 3, example 1).

15. At the time of the invention, it would have been obvious to combine JP3163127 and Yamanaka to arrive at nearly every element of the claimed invention, as discussed above. Neither reference, however, discusses the extraction of astaxanthin-containing lipids from the algal bodies.

16. Tanaka teaches a method of extracting a lipid containing astaxanthin from ruptured algae (p. 1, par. 2).

17. At the time of the invention, a method for the production of astaxanthin from green alga comprising nearly all of the claimed elements was known, as taught by JP3163127 and Yamanaka. It was further known that astaxanthin-containing lipids could be extracted from ruptured algae, as taught by Tanaka. One of ordinary skill in the art would have been motivated to combine these teachings to arrive at the claimed invention because JP3163127 and Tanaka both teach that astaxanthin extracted from green algae is desirable, and Tanaka teaches that such extraction is useful for the

production of a commercial product. One would have had a reasonable expectation of success in combining these teachings because Tanaka teaches that the extraction process can be used with alga that have been cultivated by a variety of methods (p. 3, par. 23). It would therefore have been obvious to combine the teachings of the prior art to arrive at the claimed invention.

18. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHERIDAN R. MACAULEY whose telephone number is (571)270-3056. The examiner can normally be reached on Mon-Thurs, 7:30AM-5:00PM EST, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SRM

/Ruth A. Davis/
Primary Examiner, Art Unit 1651